IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INTERCEPT PHARMACEUTICALS, INC. and INTERCEPT PHARMA EUROPE LTD.,	)	
Plaintiffs,	)	C.A. No. 20-1155 (MN)
v.	)	
LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Intercept Pharmaceuticals, Inc. ("Intercept Pharmaceuticals") and Intercept Pharma Europe Limited ("IPEL") (collectively "Intercept" or "Plaintiffs"), by their undersigned attorneys, bring this action against Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, "Lupin" or "Defendants"), and hereby allege as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq*., and in particular under 35 U.S.C. § 271, arises from Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 214980 to the United States Food and Drug Administration ("FDA"). Through this ANDA, Defendants seek approval to market a generic version of the pharmaceutical product OCALIVA® (obeticholic acid, 5 and 10 mg) prior to the expiration of U.S. Patent Nos. RE48,286 (filed June 21, 2019) ("the RE286 patent");[1] 9,238,673 (filed June 17, 2013) ("the '673 patent"); 10,047,117 (filed Nov. 20,

[1] The RE286 Patent is a reissue of U.S. Patent No. 7,138,390, which was originally asserted in this litigation. Pursuant to 35 U.S.C. § 252, the RE286 Patent contains claims that are substantially identical to those of the '390 Patent, and the RE286 Patent constitutes a continuation of the '390 Patent and has effect continuously from the issue date of the '390 Patent.

2015) ("the '117 patent"); 10,052,337 (filed Apr. 26, 2016) ("the '337 patent"); 10,174,073 (filed Apr. 25, 2017) ("the '073 patent"); and 10,758,549 (filed Feb. 11, 2020) ("the '549 patent") (collectively the "patents-in-suit"). Plaintiffs seek injunctive relief prohibiting infringement, attorneys' fees, and any other relief the Court deems just and proper.

2. This is also an action under 28 U.S.C. §§ 2201–02 for a declaratory judgment of patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and in particular under 35 U.S.C. § 271.

THE PARTIES

3. Plaintiff Intercept Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 10 Hudson Yards, 37th Floor, New York, New York 10001.

4. Plaintiff IPEL is a limited corporation organized under the laws of the United Kingdom, having a principal place of business at One Glass Wharf, Bristol, BS2 0ZX United Kingdom.

5. On information and belief, defendant Lupin Limited is a corporation organized and existing under the laws of the Republic of India, having its principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India.

6. On information and belief, defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202. On information and belief, Lupin Pharmaceuticals, Inc. is a wholly owned subsidiary of Lupin Limited.

7. On information and belief, Lupin Pharmaceuticals, Inc. acts at the direction, and for the benefit of Lupin Limited, and is controlled and/or dominated by Lupin Limited.

8. On further information and belief, Lupin Pharmaceuticals, Inc. and Lupin Limited collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Defendants are agents of each other and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

9. On information and belief, Lupin Pharmaceuticals, Inc. acts as the U.S. agent for Lupin Limited for purposes of regulatory submissions to the FDA in seeking approval for generic drugs.

10. On information and belief, Defendants prepared and submitted ANDA No. 214980 (the "Lupin ANDA") and continue to seek FDA approval of that application.

11. On information and belief, Defendants intend to commercially manufacture, market, offer for sale, and sell the products described in the Lupin ANDA (the "Lupin ANDA Products" or "ANDA Products") throughout the United States, including in the State of Delaware, in the event the FDA approves the Lupin ANDA.

JURISDICTION AND VENUE

12. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the patents-in-suit. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, and 2201–02.

13. This Court has personal jurisdiction over Defendants because, on information and belief, Defendants, *inter alia*, have continuous and systematic contacts with Delaware, regularly conduct business in Delaware, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos, have purposefully availed themselves of the privilege of

doing business in Delaware, and intend to sell the Lupin ANDA Products in Delaware upon approval of the Lupin ANDA.

14. Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware.

15. On information and belief, Defendants are in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which Defendants manufacture, distribute, market and/or sell throughout the United States and in this judicial district.

16. On information and belief, Defendants are licensed to sell generic and proprietary pharmaceutical products in Delaware, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos.

17. Defendants have committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the asserted patents that will lead to foreseeable harm and injury to Plaintiffs. On information and belief, and as indicated by a letter dated July 15, 2020 sent by Lupin Limited to Intercept Pharmaceuticals pursuant to 21 U.S.C. § 355(j)(2)(b), Defendants prepared and filed the Lupin ANDA with the intention of seeking to market the Lupin ANDA Products nationwide, including within this judicial district.

18. On information and belief, Defendants plan to sell the Lupin ANDA Products in Delaware, list the Lupin ANDA Products on Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of the Lupin ANDA Products in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos.

19. On information and belief, Defendants know and intend that the Lupin ANDA Products will be distributed and sold in Delaware and will thereby displace sales of OCALIVA®,

causing injury to Plaintiffs. Defendants intend to take advantage of their established channels of distribution in Delaware for the sale of the Lupin ANDA Products.

20. Lupin Pharmaceuticals, Inc. and Lupin Limited have engaged in patent litigation concerning FDA-approved drug products in this judicial district and have not contested personal jurisdiction or venue in this judicial district in such litigation. *See, e.g.*, *Otsuka Pharmaceuticals Co., Ltd. et al. v. Lupin Limited et al.*, No. 19-1988 (LPS) (D. Del. Feb. 10, 2020); *CyDex Pharmaceuticals, Inc. v. Lupin Limited et al.*, No. 19-2043 (LPS) (D. Del. Dec. 11, 2019); *Merck Sharp & Dohme Corp. v. Lupin Limited et al.*, No. 19-347 (RGA) (D. Del. Apr. 22, 2019); *Genentech, Inc. v. Lupin Ltd. et al.*, No. 19-109 (RGA) (D. Del. Mar. 15, 2019).

21. Additionally, this Court has personal jurisdiction over Lupin Limited because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Intercept's claims arise under federal law; (b) Lupin Limited is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Lupin Limited has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of the Lupin ANDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, including in this judicial district, such that this Court's exercise of jurisdiction over Lupin Limited satisfies due process.

22. Venue is proper in this district for Lupin Pharmaceuticals, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

23. Venue is proper in this district for Lupin Limited pursuant to 28 U.S.C. § 1391(c)(3) because, *inter alia*, Lupin Limited is a corporation organized and existing under the laws of the Republic of India and may be sued in any judicial district.

INTERCEPT'S APPROVED OCALIVA® DRUG PRODUCT AND PATENTS

24. Intercept makes and sells OCALIVA®, a product used in the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. The active ingredient in OCALIVA® is obeticholic acid. OCALIVA® is available in two strengths, 5 mg and 10 mg. A true and correct copy of the prescribing label for OCALIVA® is attached as Exhibit A.

25. Intercept Pharmaceuticals is the holder of New Drug Application ("NDA") No. 207999 for OCALIVA® and the owner of the patents-in-suit. The FDA approved NDA No. 207999 for OCALIVA® on May 27, 2016, and granted OCALIVA® five years of regulatory exclusivity for a new chemical entity pursuant to 21 C.F.R. § 314.108, which expires on May 27, 2021. The FDA also granted OCALIVA® orphan drug exclusivity pursuant to 21 C.F.R. § 316.31, which expires on May 27, 2023.

26. IPEL is the exclusive licensee of the patents-in-suit, which are listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (an FDA publication commonly known as the "Orange Book") for OCALIVA®.

27. The RE286 Patent entitled, "Steroids as Agonists for FXR," was duly and lawfully issued by the USPTO on October 27, 2020. A true and correct copy of the RE286 Patent is attached as Exhibit B.

28. The '673 Patent entitled, "Preparations and Uses of Obeticholic Acid," was duly and lawfully issued by the USPTO on January 19, 2016. A true and correct copy of the '673 Patent is attached as Exhibit C.

29. The ’117 Patent entitled, “Preparations and Uses of Obeticholic Acid,” was duly and lawfully issued by the USPTO on August 14, 2018. A true and correct copy of the ’117 Patent is attached as Exhibit D.

30. The ’337 Patent entitled, “Compositions of Obeticholic Acid and Methods of Use,” was duly and lawfully issued by the USPTO on August 21, 2018. A true and correct copy of the ’337 Patent is attached as Exhibit E.

31. The ’073 Patent entitled, “Preparations and Uses of Obeticholic Acid,” was duly and lawfully issued by the USPTO on January 8, 2019. A true and correct copy of the ’073 Patent is attached as Exhibit F.

32. The ’549 Patent entitled, “Compositions of Obeticholic Acid and Methods of Use,” was duly and lawfully issued by the USPTO on September 1, 2020. A true and correct copy of the ’549 Patent is attached as Exhibit G.

LUPIN’S ANDA

33. On information and belief, Lupin has submitted or caused to be submitted ANDA No. 214980 to the FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of obeticholic acid tablets, as a purported generic version of OCALIVA®, prior to the expiration of the patents-in-suit.

34. On information and belief, on or about July 15, 2020, Lupin Limited mailed a letter to Intercept Pharmaceuticals regarding “Notice of Paragraph IV Certification Regarding U.S. Patent Nos. 7,138,390; 9,238,673; 10,047,117; 10,052,337; and 10,174,073 Pursuant to Section 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R § 314.95 for ANDA No. 214980” (the “First Notice Letter”). The First Notice Letter represented that Lupin had submitted to the FDA the Lupin ANDA and a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the product described in the

Lupin ANDA before the expiration of patents listed in the Orange Book for OCALIVA®. Hence, Lupin's purpose in submitting the Lupin ANDA is to manufacture and market the ANDA Products before the expiration of the patents-in-suit.

35. Lupin's First Notice Letter stated that the Paragraph IV certification in the Lupin ANDA alleges that the '390,[2] '673, '117, '337, and '073 Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Products.

36. Lupin's First Notice Letter contained a purported detailed statement of the factual and legal basis for its Paragraph IV certification ("First Detailed Statement").

37. On information and belief, on or about September 28, 2020, Lupin Limited mailed a letter to Intercept Pharmaceuticals regarding a purported notice of Paragraph IV certification regarding U.S. Patent No. 10,758,549 pursuant to Section 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R § 314.95 for ANDA No. 214980 (the "Second Notice Letter"). The Second Notice Letter represented that Lupin had submitted to the FDA a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the product described in the Lupin ANDA before the expiration of a patent listed in the Orange Book for OCALIVA®, the '549 Patent. Hence, Lupin's purpose in submitting the Lupin ANDA is to manufacture and market the ANDA Products before the expiration of the '549 Patent.

38. Lupin's Second Notice Letter stated that the Paragraph IV certification in the Lupin ANDA alleges that the '549 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Products.

39. Lupin's Second Notice Letter contained a purported detailed statement of the factual and legal basis for its Paragraph IV certification ("Second Detailed Statement").

[2] Plaintiffs' original complaint alleged infringement of the '390 Patent, which has now been reissued as the RE286 patent.

40. On information and belief, on or about November 10, 2020, Lupin Limited mailed a letter to Intercept Pharmaceuticals regarding a purported "Notice of Paragraph IV Certification Regarding U.S. Patent No. RE48,286 Pursuant to Section 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R § 314.95 for ANDA No. 214980" (the "Third Notice Letter"). The Third Notice Letter represented that Lupin had submitted to the FDA a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the product described in the Lupin ANDA before the expiration of a patent listed in the Orange Book for OCALIVA®, the RE286 Patent. Hence, Lupin's purpose in submitting the Lupin ANDA is to manufacture and market the ANDA Products before the expiration of the RE286 Patent.

41. Lupin's Third Notice Letter stated that the Paragraph IV certification in the Lupin ANDA alleges that the RE286 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Products.

42. Lupin's Third Notice Letter contained a purported detailed statement of the factual and legal basis for its Paragraph IV certification ("Third Detailed Statement").

43. On information and belief, Defendants have participated in the preparation and submission of the Lupin ANDA, have provided material support to the preparation and submission of the Lupin ANDA, and intend to support the further prosecution of the Lupin ANDA.

44. On information and belief, if the FDA approves the Lupin ANDA, Defendants will manufacture, offer for sale, or sell the ANDA Products within the United States, including within Delaware, or will import the ANDA Products into the United States, including Delaware.

45. Alternatively, on information and belief, if the FDA approves the Lupin ANDA, Defendants will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Products.

46. This action was filed within forty-five days of Intercept Pharmaceuticals' receipt of the First Notice Letter. This First Amended Complaint is being filed within forty-five days of receipt of the Second Notice Letter and within forty-five days of receipt of the Third Notice Letter.

COUNT I
INFRINGEMENT OF THE RE286 PATENT

47. Plaintiffs incorporate by reference paragraphs 1–46 as if fully set forth herein.

48. On information and belief, Defendants have submitted or caused the submission of the Lupin ANDA to the FDA and continue to seek FDA approval of the Lupin ANDA.

49. Defendants have infringed the RE286 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Lupin ANDA with a Paragraph IV certification and seeking FDA approval of the Lupin ANDA prior to the expiration of the RE286 Patent.

50. On information and belief, if the Lupin ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, or otherwise distribute the ANDA Products in the United States, directly infringing the RE286 Patent.

51. On information and belief, upon FDA approval of the Lupin ANDA, Defendants will market and distribute the Lupin ANDA Products to resellers, pharmacies, health care professionals, and end users of the Lupin ANDA Products. Accompanying the Lupin ANDA Products, Defendants will also knowingly and intentionally include a product label and insert containing instructions for administering the Lupin ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Lupin ANDA Products to directly infringe one or more claims of the RE286 Patent. In addition,

on information and belief, Defendants will encourage acts of direct infringement with knowledge of the RE286 Patent and knowledge that they are encouraging infringement.

52. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Products would actively induce and/or contribute to infringement of the RE286 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 214980, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the RE286 Patent.

53. Defendants had actual knowledge of the '390 Patent prior to filing the Lupin ANDA. Defendants filed the Lupin ANDA without a reasonable basis for asserting the '390 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. The RE286 Patent contains claims that are substantially identical to the '390 Patent. Thus, Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the RE286 Patent renders this case "exceptional" under 35 U.S.C. § 285.

54. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the RE286 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE RE286 PATENT

55. Plaintiffs incorporate by reference paragraphs 1–54 as if fully set forth herein.

56. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

57. On information and belief, if the Lupin ANDA is approved, the ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, by or through Defendants and their affiliates.

58. On information and belief, Defendants know that health care professionals or patients will use the ANDA Products in accordance with the labeling sought by the Lupin ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the RE286 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

59. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Products complained of herein will begin immediately after the FDA approves the Lupin ANDA. Any such conduct before the RE286 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the RE286 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

60. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the RE286 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

61. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

62. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT III
INFRINGEMENT OF THE '673 PATENT

63. Plaintiffs incorporate by reference paragraphs 1–62 as if fully set forth herein.

64. On information and belief, Defendants have submitted or caused the submission of the Lupin ANDA to the FDA and continue to seek FDA approval of the Lupin ANDA.

65. Defendants have infringed the '673 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Lupin ANDA with a Paragraph IV certification and seeking FDA approval of the Lupin ANDA prior to the expiration of the '673 Patent.

66. On information and belief, if the Lupin ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, or otherwise distribute the ANDA Products in the United States, directly infringing the '673 Patent.

67. On information and belief, upon FDA approval of the Lupin ANDA, Defendants will market and distribute the Lupin ANDA Products to resellers, pharmacies, health care professionals, and end users of the Lupin ANDA Products. Accompanying the Lupin ANDA Products, Defendants will also knowingly and intentionally include a product label and insert containing instructions for administering the Lupin ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Lupin ANDA Products to directly infringe one or more claims of the '673 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '673 Patent and knowledge that they are encouraging infringement.

68. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Products would actively induce and/or contribute to infringement

of the ’673 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 214980, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the ’673 Patent.

69. Defendants had actual knowledge of the ’673 Patent prior to filing the Lupin ANDA. Defendants filed the Lupin ANDA without a reasonable basis for asserting the ’673 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants’ conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the ’673 Patent renders this case “exceptional” under 35 U.S.C. § 285.

70. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the ’673 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT IV
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’673 PATENT

71. Plaintiffs incorporate by reference paragraphs 1–70 as if fully set forth herein.

72. Plaintiffs’ claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

73. On information and belief, if the Lupin ANDA is approved, the ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, by or through Defendants and their affiliates.

74. On information and belief, Defendants know that health care professionals or patients will use the ANDA Products in accordance with the labeling sought by the Lupin ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '673 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

75. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Products complained of herein will begin immediately after the FDA approves the Lupin ANDA. Any such conduct before the '673 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '673 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

76. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the '673 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

77. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

78. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT V
INFRINGEMENT OF THE '117 PATENT

79. Plaintiffs incorporate by reference paragraphs 1–78 as if fully set forth herein.

80. On information and belief, Defendants have submitted or caused the submission of the Lupin ANDA to the FDA and continue to seek FDA approval of the Lupin ANDA.

81. Defendants have infringed the '117 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Lupin ANDA with a Paragraph IV certification and seeking FDA approval of the Lupin ANDA prior to the expiration of the '117 Patent.

82. On information and belief, if the Lupin ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, or otherwise distribute the ANDA Products in the United States, directly infringing the '117 Patent.

83. On information and belief, upon FDA approval of the Lupin ANDA, Defendants will market and distribute the Lupin ANDA Products to resellers, pharmacies, health care professionals, and end users of the Lupin ANDA Products. Accompanying the Lupin ANDA Products, Defendants will also knowingly and intentionally include a product label and insert containing instructions for administering the Lupin ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Lupin ANDA Products to directly infringe one or more claims of the '117 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '117 Patent and knowledge that they are encouraging infringement.

84. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Products would actively induce and/or contribute to infringement of the '117 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 214980, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '117 Patent.

85. Defendants had actual knowledge of the '117 Patent prior to filing the Lupin ANDA. Defendants filed the Lupin ANDA without a reasonable basis for asserting the '117 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '117 Patent renders this case "exceptional" under 35 U.S.C. § 285.

86. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '117 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VI
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '117 PATENT

87. Plaintiffs incorporate by reference paragraphs 1–86 as if fully set forth herein.

88. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

89. On information and belief, if the Lupin ANDA is approved, the ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, by or through Defendants and their affiliates.

90. On information and belief, Defendants know that health care professionals or patients will use the ANDA Products in accordance with the labeling sought by the Lupin ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '117 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

91. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Products complained of herein will begin immediately after the FDA approves the Lupin ANDA. Any such conduct before the '117 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '117 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

92. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the '117 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

93. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

94. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT VII
INFRINGEMENT OF THE '337 PATENT

95. Plaintiffs incorporate by reference paragraphs 1–94 as if fully set forth herein.

96. On information and belief, Defendants have submitted or caused the submission of the Lupin ANDA to the FDA and continue to seek FDA approval of the Lupin ANDA.

97. Defendants have infringed the '337 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Lupin ANDA with a Paragraph IV certification and seeking FDA approval of the Lupin ANDA prior to the expiration of the '337 Patent.

98. On information and belief, if the Lupin ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, or otherwise distribute the ANDA Products in the United States, directly infringing the '337 Patent.

99. On information and belief, upon FDA approval of the Lupin ANDA, Defendants will market and distribute the Lupin ANDA Products to resellers, pharmacies, health care professionals, and end users of the Lupin ANDA Products. Accompanying the Lupin ANDA Products, Defendants will also knowingly and intentionally include a product label and insert containing instructions for administering the Lupin ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Lupin ANDA Products to directly infringe one or more claims of the '337 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '337 Patent and knowledge that they are encouraging infringement.

100. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Products would actively induce and/or contribute to infringement of the '337 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 214980, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '337 Patent.

101. Defendants had actual knowledge of the '337 Patent prior to filing the Lupin ANDA. Defendants filed the Lupin ANDA without a reasonable basis for asserting the '337 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity, unenforceability,

and/or non-infringement with respect to the '337 Patent renders this case "exceptional" under 35 U.S.C. § 285.

102. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '337 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VIII
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '337 PATENT

103. Plaintiffs incorporate by reference paragraphs 1–102 as if fully set forth herein.

104. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

105. On information and belief, if the Lupin ANDA is approved, the ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, by or through Defendants and their affiliates.

106. On information and belief, Defendants know that health care professionals or patients will use the ANDA Products in accordance with the labeling sought by the Lupin ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '337 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

107. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Products complained of herein will begin immediately after the FDA approves the Lupin ANDA. Any such conduct before the '337 Patent expires will contribute to the infringement of and/or induce the infringement

of one or more claims of the '337 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

108. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the '337 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

109. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

110. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT IX
INFRINGEMENT OF THE '073 PATENT

111. Plaintiffs incorporate by reference paragraphs 1–110 as if fully set forth herein.

112. On information and belief, Defendants have submitted or caused the submission of the Lupin ANDA to the FDA and continue to seek FDA approval of the Lupin ANDA.

113. Defendants have infringed the '073 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Lupin ANDA with a Paragraph IV certification and seeking FDA approval of the Lupin ANDA prior to the expiration of the '073 Patent.

114. On information and belief, if the Lupin ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, or otherwise distribute the ANDA Products in the United States, directly infringing the '073 Patent.

115. On information and belief, upon FDA approval of the Lupin ANDA, Defendants will market and distribute the Lupin ANDA Products to resellers, pharmacies, health care

professionals, and end users of the Lupin ANDA Products. Accompanying the Lupin ANDA Products, Defendants will also knowingly and intentionally include a product label and insert containing instructions for administering the Lupin ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Lupin ANDA Products to directly infringe one or more claims of the '073 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '073 Patent and knowledge that it is encouraging infringement.

116. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Products would actively induce and/or contribute to infringement of the '073 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 214980, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '073 Patent.

117. Defendants had actual knowledge of the '073 Patent prior to filing the Lupin ANDA. Defendants filed the Lupin ANDA without a reasonable basis for asserting the '073 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '073 Patent renders this case "exceptional" under 35 U.S.C. § 285.

118. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '073 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and

Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT X
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '073 PATENT

119. Plaintiffs incorporate by reference paragraphs 1–118 as if fully set forth herein.

120. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

121. On information and belief, if the Lupin ANDA is approved, the ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, by or through Defendants and their affiliates.

122. On information and belief, Defendants know that health care professionals or patients will use the ANDA Products in accordance with the labeling sought by the Lupin ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '073 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

123. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Products complained of herein will begin immediately after the FDA approves the Lupin ANDA. Any such conduct before the '073 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '073 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

124. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement

of the ’073 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

125. Plaintiffs will be substantially and irreparably harmed by Defendants’ infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

126. This case is exceptional, and Plaintiffs are entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT XI
INFRINGEMENT OF THE ’549 PATENT

127. Plaintiffs incorporate by reference paragraphs 1–126 as if fully set forth herein.

128. On information and belief, Defendants have submitted or caused the submission of the Lupin ANDA to the FDA and continue to seek FDA approval of the Lupin ANDA.

129. Defendants have infringed the ’549 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Lupin ANDA with a Paragraph IV certification and seeking FDA approval of the Lupin ANDA prior to the expiration of the ’549 Patent.

130. On information and belief, if the Lupin ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, or otherwise distribute the ANDA Products in the United States, directly infringing the ’549 Patent.

131. On information and belief, upon FDA approval of the Lupin ANDA, Defendants will market and distribute the Lupin ANDA Products to resellers, pharmacies, health care professionals, and end users of the Lupin ANDA Products. Accompanying the Lupin ANDA Products, Defendants will also knowingly and intentionally include a product label and insert containing instructions for administering the Lupin ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of

the Lupin ANDA Products to directly infringe one or more claims of the '549 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '549 Patent and knowledge that they are encouraging infringement.

132. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Products would actively induce and/or contribute to infringement of the '549 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 214980, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '549 Patent.

133. Defendants had actual knowledge of the '549 Patent prior to filing the Paragraph IV certification to the Lupin ANDA, and were aware that submitting a Paragraph IV certification requesting FDA approval prior to the expiration of the '549 Patent would constitute an act of infringement of the '549 Patent. Defendants filed the Paragraph IV certification to the Lupin ANDA without a reasonable basis for asserting the '549 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '549 Patent renders this case "exceptional" under 35 U.S.C. § 285.

134. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '549 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT XII
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '549 PATENT

135. Plaintiffs incorporate by reference paragraphs 1–134 as if fully set forth herein.

136. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

137. On information and belief, if the Lupin ANDA is approved, the ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, by or through Defendants and their affiliates.

138. On information and belief, Defendants know that health care professionals or patients will use the ANDA Products in accordance with the labeling sought by the Lupin ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '549 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

139. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Products complained of herein will begin immediately after the FDA approves the Lupin ANDA. Any such conduct before the '549 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '549 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

140. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the '549 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

141. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

142. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Defendants have infringed the RE286, '673, '117, '337, '073, and '549 Patents under 35 U.S.C. § 271(e)(2)(A);

B. A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g), Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the RE286, '673, '117, '337, '073, and '549 Patents;

C. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their affiliates and subsidiaries, and all persons and entities acting in concert with Defendants from commercially manufacturing, using, offering for sale, or selling or importing any product that infringes the RE286, '673, '117, '337, '073, or '549 Patents, including the ANDA Products described in ANDA No. 214980;

D. The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of ANDA No. 214980 shall be no earlier than the expiration date of the RE286, '673, '117, '337, '073, and '549 Patents, or any later expiration of exclusivity for the RE286, '673, '117, '337, '073, and '549 Patents, including any extensions or regulatory exclusivities;

E. A declaration under 28 U.S.C. § 2201 that if Defendants, their officers, agents, servants, employees, licensees, representatives, and attorneys, and any other persons acting or attempting to act in active concert or participation with them or acting on their behalf, engage in the commercial manufacture, use, offer for sale, sale and/or importation of the product described in ANDA No. 214980, it will constitute an act of direct and/or indirect infringement of the RE286, '673, '117, '337, '073, and '549 Patents;

F. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, or any product that infringes the RE286, '673, '117, '337, '073, and '549 Patents, or induce or contribute to such conduct, prior to the expiration of the RE286, '673, '117, '337, '073, and '549 Patents, or any later expiration of exclusivity for the RE286, '673, '117, '337, '073, and '549 Patents, including any extensions or regulatory exclusivities;

G. The entry of judgment declaring that Defendants' acts render this case an exceptional case, and awarding Plaintiffs their attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

H. An award to Plaintiffs of their costs and expenses in this action; and

I. Such other and further relief as the Court may deem just and proper.

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November 12, 2020

CERTIFICATE OF SERVICE

I hereby certify that on November 12, 2020, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on November 12, 2020, upon the following in the manner indicated:

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